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In the Supreme Court of the United States

WARNER-LAMBERT COMPANY LLC and PFIZER INC.,

Petitioners,

v.

KIMBERLY KENT, *et al.*,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Second Circuit

BRIEF OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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BRIEF OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

INTEREST OF THE *AMICUS CURIAE*

The Chamber of Commerce of the United States of America ("the Chamber") is the world's largest business federation.[1] The Chamber represents an underlying membership of more than three million companies and professional organizations of every size, in every industry sector, and from every region of the country. An important function of the Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and the courts. To that end, the Chamber regularly files *amicus* briefs in cases that raise issues of vital concern to the Nation's business community.

The Chamber is well situated to address the issues of federal preemption raised by this case. It has filed *amicus* briefs in many of the Court's leading preemption cases. Its members are engaged in commerce in each of the 50 States and are subject in varying degrees to a wide range of federal regulations, including comprehensive regulatory schemes for product approval such as the one administered by the Food and Drug Administration ("FDA"). Accordingly, its members often confront the interplay be-

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[1] The parties have each filed letters giving blanket consent to the filing of *amicus* briefs in this case. No counsel for a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than *amicus curiae*, its members, or its counsel made a monetary contribution to the preparation or submission of this brief.

tween approval of a product by a federal agency and the potential for state common-law tort liability.

The Chamber's members are particularly concerned about the threat that courts will employ the vague and inconsistently applied "presumption against preemption" doctrine to elide actual conflicts between federal and state law, as the Second Circuit did below.[2] The Chamber is not only capable of offering a broader perspective on the role of that presumption than the parties may provide, but also is keenly interested in ensuring that the manner in which courts apply the presumption is consistent, clear, and rational.

INTRODUCTION AND SUMMARY OF ARGUMENT

By statute, Michigan law affords a pharmaceutical manufacturer complete immunity against a product liability action if it can demonstrate that the allegedly defective product at issue "received the FDA's approval and complied with the FDA's labeling and substantive requirements." Pet. App. 6a; see MICH. COMP. LAWS § 600.2946(5). This statutory immunity does not apply, however, if the plaintiff can

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[2] There is a split among the courts of appeals over whether the presumption against preemption applies to an analysis of conflict preemption. Compare *Wuebker* v. *Wilbur-Ellis Co.*, 418 F.3d 883, 887-889 (8th Cir. 2005) (applying presumption); *Oxygenated Fuels Ass'n* v. *Davis*, 331 F.3d 665, 673 (9th Cir. 2003) (same); *Green* v. *Fund Asset Mgmt., L.P.*, 245 F.3d 214, 223-224 (3d Cir. 2001) (same), with *Irving* v. *Mazda Motor Corp.*, 136 F.3d 764, 769 (11th Cir. 1998) ("When considering implied preemption, no presumption exists against preemption."); *Perry* v. *Mercedes Benz of N. Am., Inc.*, 957 F.2d 1257, 1261 (5th Cir. 1992) ("we do not begin with an assumption against *conflict* preemption").

demonstrate that the manufacturer, "at any time before the event that allegedly caused the injury," Pet. App. 6a, "[i]ntentionally withh[eld] from or misrepresent[ed] to the [FDA] information concerning the drug that is required to be submitted under the [Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.*], and [that] the drug would not have been approved, or the [FDA] would have withdrawn approval for the drug if the information [had been] accurately submitted." MICH. COMP. LAWS § 600.2946(5)(a). This case addresses whether this statutory exception to immunity "inevitably conflict[s]" with, and is impliedly preempted by, the FDA's responsibilities under federal law to approve pharmaceutical products and to "police fraud consistently with the Administration's judgment and objectives." *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001).

In the course of determining that Michigan's statutory exception to immunity was not impliedly preempted, the court of appeals invoked a "presumption against federal preemption of state law." Pet. App. 18a. The court acknowledged that this Court had established in *Buckman* that no such presumption should apply when a State "invent[s] new causes of action premised on fraud against the FDA," *ibid.*, because "'[p]olicing fraud against federal agencies is hardly a field which the States have traditionally occupied.'" *Ibid.* (quoting *Buckman*, 531 U.S. at 347) (emphasis removed). However, the Second Circuit distinguished this Court's refusal to invoke the presumption against preemption in *Buckman* on the ground that plaintiffs' "cause[s] of action" in this case, which survived Michigan's statutory immunity through operation of the exception, could not "rea-

sonably be characterized as a state's attempt to police fraud against the FDA." *Ibid.*

According to the court of appeals, Michigan's "legislative scheme" instead had "[t]he object * * * to regulate and restrict when victims could continue to recover under *preexisting* state products liability law." Pet. App. 18a (emphasis added). Because "[t]he Michigan legislature's desire to rein in state-based tort liability falls squarely within its prerogative to 'regulate matters of health and safety,'" the court of appeals reasoned, *id.* at 19a (quoting *Buckman*, 531 U.S. at 348; alterations omitted), the presumption—far from not applying at all—should instead "stand[] at its strongest." *Ibid.*[3]

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[3] There can be no question that the court of appeals' invocation of the presumption against preemption skewed its preemption analysis significantly. See Pet. App. 19a ("the existence of the presumption in the instant case requires an altogether different analysis from that made in *Buckman*"); *id.* at 19a n.6 ("This fact also substantially diminishes the persuasive effect of the federal law analysis made in *Garcia* [v. *Wyeth-Ayerst Labs.*, 385 F.3d 961 (6th Cir. 2004)], since the Sixth Circuit's holding in *Garcia* was based on the assumption that no presumption against preemption applied."); *id.* at 20a & n.7 (characterizing refusal to find that "Congress, without any explicit expression of intent * * * modified (and, in effect, gutted) traditional state law duties between pharmaceutical companies and their customers" as "another way of saying that, unlike the situation in *Buckman*, the presumption against preemption is at its strongest in the instant case"); *id.* at 24a (declining to find preemption in absence of "explicit[]" statement of Congress's intent) (quoting recitation of presumption in *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470, 485 (1996)); *id.* at 27a ("The appeal before us presents a very different set of circumstances, one in which there is a clear presumption against preemption of long-standing common law claims.").

Petitioners' brief addresses in detail the language and purpose of the statutes and regulations that govern this case, and demonstrates why Michigan's statutory exception to immunity is preempted under well-established principles. Rather than duplicate those arguments here, we focus on a more broadly applicable and doctrinally significant aspect of the court of appeals' decision: that court's application of the so-called presumption against preemption. This element of the Second Circuit's holding was seriously flawed and has pernicious implications for a wide variety of other cases.

I. The time has come for this Court to clarify once and for all that the presumption against preemption simply does not apply to the analysis of whether state law conflicts with federal law. Although the Court has at times invoked the presumption when analyzing claims of *field* and *express* preemption (albeit inconsistently and controversially), it almost never has done so when addressing claims of *conflict* preemption. Moreover, in recent decisions involving conflict preemption, the Court's approach—in emphasizing ordinary principles of statutory interpretation and the inapplicability of any additional burdens prior to a finding of preemption—has cast significant doubt on whether the presumption has any relevance to a conflict preemption analysis.

Foundational and long-recognized principles of constitutional law and statutory construction fully justify the Court's consistent recent pattern of failing to apply the presumption when engaging in a conflict preemption analysis. As a preliminary matter, there is no textual basis in the Constitution for applying such a presumption in any circumstance, and the Court has never addressed the serious challenges

that have been levied against the free-form concept of "federalism concerns," which has been invoked to justify such a presumption. Regardless, conflict preemption is fundamentally different from field and express preemption—the strands of preemption doctrine in which the Court traditionally has applied the presumption—in that it does not require a court to infer Congress's preemptive intent. Determining whether there is an actual conflict between state and federal law instead requires a judicial interpretation of the substantive—as opposed to the preemptive—meaning of a statute. As this Court has made clear, such a substantive interpretation does not implicate the presumption. Once an actual conflict has been identified as a matter of substantive law, a finding of preemption follows inescapably from the Supremacy Clause.

II. Even if the presumption against preemption were ever applicable to a conflict preemption analysis, the lower court nonetheless would have erred in invoking that presumption here. As this Court held in *Buckman*, preemption of a state law that bears upon the inherently federal relationship between the FDA and a pharmaceutical manufacturer poses no threat to the historic primacy of state regulation in matters of health and safety.

There is no legitimate basis for distinguishing between a *cause of action* predicated on a finding of fraud on the FDA, as in *Buckman*, and a fraud-on-the-FDA *exception* to a generalized grant of statutory immunity from common law liability. Both necessitate a state court's independent inquiry into the adequacy and veracity of submissions to the FDA as a predicate requirement to establishing liability under state tort law. A state cannot so directly intrude into

the federal realm without losing any entitlement to the presumption against preemption that it might enjoy when regulating solely in those fields that have traditionally been the subject of state law.

In reaching the contrary conclusion, the court of appeals both mischaracterized the nature of the preemption at issue in this case and failed to apply the analysis mandated by this Court's precedents. This case does not involve the preemption of a state-law cause of action, as the court of appeals erroneously assumed; a finding of federal preemption would not itself preclude a plaintiff from asserting any state-law cause of action. Similarly, because the state law actually subject to preemption is merely the Michigan statutory exception to immunity, the court of appeals erred in focusing on the underlying state law causes of action, which it deemed "preexisting," "traditional," and "long-standing." Pet. App. 18a, 27a. The proper focus instead should have been on the statutory exception to immunity, which is of recent vintage and which necessarily bears upon an inherently federal relationship.

The court of appeals' conclusion that the presumption against preemption in this case "stands at its strongest," Pet. App. 19a, also rests on two other significant misinterpretations of this Court's precedents. First, the court of appeals sought to discern the Michigan legislature's motivation in enacting the immunity exception, although this Court has squarely rejected such reliance on a review of a legislature's motives. Second, the court of appeals ignored the primary lesson of *Buckman* with respect to the presumption against preemption: a state law that bears upon an inherently federal relationship is not entitled to the presumption because it does not

threaten the historic primacy of state regulation in matters of health and safety.

ARGUMENT

I. The Presumption Against Preemption Is Inapplicable To The Determination Whether State Law Actually Conflicts With Federal Law.

This Court's recent case law, as well as established principles of constitutional law and statutory construction, afford strong grounds for concluding that no presumption against preemption applies to the judicial determination of whether preemption is necessary because of an "actual conflict" between state law and valid federal law. *Geier* v. *Am. Honda Motor Co.*, 529 U.S. 861, 884 (2000).[4] Accordingly, the Court should end years of ambiguity and avoidance of this question and clarify that a court may not invoke the presumption when analyzing claims of conflict preemption.

A. This Court's recent decisions demonstrate that the presumption against preemption does not apply to a conflict preemption analysis.

As a general matter, the Court's adherence to the presumption against preemption—usually described

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[4] The Court's precedents establish that such an "actual conflict" exists (i) where it is impossible for a private party to comply with both state and federal requirements, or (ii) where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress. See, *e.g.*, *English* v. *Gen. Elec. Co.*, 496 U.S. 72, 79 (1990). There is no "legal wedge" between, and thus "no grounds * * * for attempting to distinguish," these two manifestations of actual conflict. *Geier*, 529 U.S. at 873–874.

as a requirement that Congress make its preemptive intent "clear and manifest" "[i]n areas of traditional state regulation," *Bates* v. *Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005) (internal quotation marks omitted); see also *Lohr*, 518 U.S. at 485—has been inconsistent and controversial. The Court's earliest Supremacy Clause cases made no mention of such a presumption, or of any analogous principle of special treatment for any state laws. See, *e.g.*, *Martin* v. *Hunter's Lessee*, 14 U.S. (1 Wheat.) 304, 343–344 (1816); *Ware* v. *Hylton*, 3 U.S. (3 Dall.) 199 (1796) (applying no presumption in case where treaty superseded state criminal law); see also *Gibbons* v. *Ogden*, 22 U.S. (9 Wheat.) 1, 210 (1824) ("[I]t will be immaterial whether those laws were passed * * * in virtue of a power to regulate [the several States'] domestic trade and police. * * * [T]he acts of [the State] must yield to the law of Congress."). Indeed, during the first several decades of the 20th century the Court recognized a strong generalized presumption *in favor* of preemption. See Mary J. Davis, *Unmasking The Presumption in Favor of Preemption*, 53 S.C. L. REV. 967, 973–983 (2002).

It was not until 1947 that this Court first explicitly recognized the existence of an "assumption" of nonpreemption of the "historic police powers of the States," applicable when "Congress legislate[s] * * * in [a] field which the States have traditionally occupied." *Rice* v. *Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). See Stephen A. Gardbaum, *The Nature of Preemption*, 79 CORNELL L. REV. 767, 806–807 (1994). At issue in *Rice* was whether Congress had displaced all state law in a particular field, and the Court subsequently has at times applied this assumption of nonpreemption (also characterized as a "presumption against preemption") when analyzing

such claims of "field" preemption.[5] The Court also has applied the doctrine when interpreting express statutory preemption provisions, see, *e.g.*, *Bates*, 544 U.S. at 449; *Lohr*, 518 U.S. at 485; *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504, 518 (1992)—although the application of the presumption in this context has not been without controversy. See, *e.g.*, *Engine Mfrs. Ass'n* v. *S. Coast Air Quality Mgmt. Dist.*, 541 U.S. 246, 256 (2004) (noting that "not all Members of this Court agree" on the "application" of the "presumption against pre-emption") (internal quotation marks omitted).[6]

By contrast, the Court almost without exception has avoided reliance on the presumption when addressing claims of conflict preemption.[7] It is true

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[5] See, *e.g.*, *English*, 496 U.S. at 79; *Hillsborough County* v. *Automated Med. Labs., Inc.*, 471 U.S. 707, 716 (1985); but see *Silkwood* v. *Kerr-McGee Corp.*, 464 U.S. 238, 247 (1984) (field preemption analysis makes no mention of presumption).

[6] At least two current members of the Court reject the presumption's applicability in interpreting the scope of express preemption provisions. See, *e.g.*, *Bates*, 544 U.S. at 457 (Thomas, J., concurring in the judgment in part and dissenting in part); *Cipollone*, 505 U.S. at 544 (Scalia, J., concurring in the judgment in part and dissenting in part); see also *Engine Mfrs. Ass'n*, 541 U.S. at 256.

[7] See, *e.g.*, *Sprietsma* v. *Mercury Marine*, 537 U.S. 51 (2002); *Geier*, 529 U.S. 861; *United States* v. *Locke*, 529 U.S. 89 (2000); *Crosby* v. *Nat'l Foreign Trade Council*, 530 U.S. 363 (2000); *Freightliner Corp.* v. *Myrick*, 514 U.S. 280 (1995); *Gade* v. *Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88 (1992) (plurality); *La. Pub. Serv. Comm'n* v. *FCC*, 476 U.S. 355 (1986); *Wis. Dep't of Indus., Labor & Human Relations* v. *Gould Inc.*, 475 U.S. 282 (1986); *Allis-Chalmers Corp.* v. *Lueck*, 471 U.S. 202 (1985); *Brown* v. *Hotel & Rest. Employees & Bartenders Int'l Union Local 54*, 468 U.S. 491 (1984); *Capital Cities Cable, Inc.* v. *Crisp*, 467 U.S. 691 (1984).

that, in *Hillsborough County* and *California* v. *ARC American Corp.*, 490 U.S. 93 (1989), the Court did preface its conflict preemption analysis with a nod to the presumption. See 471 U.S. at 715–716; 490 U.S. at 101. In neither case, however, did the Court rely on the presumption in the actual conflict preemption analysis itself.[8] Moreover, as the Court later observed in its unanimous opinion in *Locke*, such mere "'prefatory'" references to the presumption in a decision do not establish that it actually was deemed applicable under the circumstance of that case. 529 U.S. at 90, 107–108 (citing *Ray* v. *Atl. Richfield Co.*, 435 U.S. 151, 157 (1978)).[9] Indeed, in *Crosby*, decided in 2000, the Court recognized that the applicability of the presumption in the conflict preemption context remained an open question. 530 U.S. at 374 n.8 ("We leave for another day a consideration in this context of a presumption against preemption.").

Although the Court has not addressed the issue directly, the analyses in several recent decisions have cast into significant doubt whether the presumption has any relevance in conflict preemption cases.

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[8] See *ARC Am. Corp.*, 490 U.S. at 105–106 (holding that "congressional purposes * * * provide no support for a finding that state [law is] pre-empted by federal law"); *Hillsborough County*, 471 U.S. at 722 ("In summary, given the findings of the District Court, the lack of any evidence in the record of a threat to the adequacy of the plasma supply, and the significance that we attach to the lack of a statement by the FDA, we conclude that [there is no conflict].") (internal quotation marks omitted).

[9] At least two post-*Rice* decisions addressing claims of both conflict and field preemption pointedly invoked the presumption only with reference to their field preemption analyses. See, *e.g.*, *Int'l Paper Co.* v. *Ouellette*, 479 U.S. 481, 491 (1987); *Jones* v. *Rath Packing Co.*, 430 U.S. 519, 525 (1977).

The Court's most notable recent precedent bearing on this issue is *Geier*. In *Geier*, the Court held that federal law—a safety standard promulgated by the Department of Transportation under the National Traffic and Motor Vehicle Safety Act of 1966, in conjunction with that Act itself—preempted a state law tort action seeking to impose liability on an automobile manufacturer for failing to install an airbag. 529 U.S. at 881. A state law duty requiring automobile manufacturers to install airbags plausibly could be characterized as a core example of "state police power regulations," *Cipollone*, 505 U.S. at 518, "in a field which the States have traditionally occupied." *Lohr*, 518 U.S. at 485 (internal quotation marks omitted). Nevertheless, the majority in *Geier* never mentioned any presumption against preemption. See *Geier*, 529 U.S. at 906–907 (Stevens, J., dissenting) ("the Court simply ignores the presumption [against preemption], preferring instead to put the burden on petitioners to show that their tort claim would not frustrate [federal] purposes").

Instead, the *Geier* majority strongly implied that the presumption has no relevance to a conflict preemption analysis, emphasizing that the Court was applying "longstanding," "ordinary," and "experience-proved principles of conflict pre-emption." *Geier*, 529 U.S. at 874. Under these principles, preemption is necessary if there is a "demonstration of actual conflict" between state and federal law, with no additional "burden" weighing the scales either against or in favor of preemption. *Id.* at 874, 883. There were no grounds "for attempting to distinguish among types of federal-state conflict for purposes of analyzing whether such a conflict warrants pre-emption in a particular case." *Id.* at 874. Indeed, the Court explicitly acknowledged and dismissed one of the dissent's

principal arguments in favor of invoking the presumption—the need for "a limiting principle that prevents federal judges from running amok with our potentially boundless (and perhaps inadequately considered) doctrine of implied conflict pre-emption based on frustration of purposes" (*id.* at 907) (Stevens, J., dissenting). See *id.* at 873–874.

Other recent decisions of the Court are consistent with *Geier*'s apparent rejection of the presumption in conflict preemption cases. For example, in *Locke*, the Court unanimously termed the presumption "artificial," declining to invoke it in analyzing whether federal law conflicted with state regulations in "an area where there has been a history of significant federal presence." 529 U.S. at 108. And, in *Sprietsma*, the Court made no mention of the presumption in holding that the Coast Guard's decision—pursuant to authority granted by federal law, see 46 U.S.C. § 4302—not to require propeller guards on boat motors did not conflict with a duty to install such guards sounding in state tort law. 537 U.S. at 64–68.[10] The Court's holding in *Sprietsma* turned on the failure of the Coast Guard to "convey an authoritative message of a federal policy against propeller guards"—a regulatory choice that the Court explicitly contrasted to "the decision of the Secretary of Transportation that was given pre-emptive effect in *Geier*." *Id.* at 67 (internal quotation marks and cita-

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[10] By contrast, the Court did reference the presumption in passing in its analysis (and rejection) of possible *field* preemption under the relevant federal statute. See *Sprietsma*, 537 U.S. at 69 (observing that the "structure and framework" of federal statute "do not convey a clear and manifest intent to * * * implicitly pre-empt all state common law relating to boat manufacture") (internal quotation marks and citation omitted).

tion omitted). Indeed, the Court suggested that, as in *Geier*, such an authoritative message, if it had been delivered, would have been "inconsistent with a tort verdict premised on a jury's finding that" a propeller guard was required, *ibid.*—speculation that hardly is consistent with the existence of a presumption weighing in favor of the survival of state law.[11]

B. Foundational and long-recognized principles preclude application of the presumption against preemption to a conflict preemption analysis.

The persistent refusal of the Court to invoke the presumption against preemption when analyzing conflict preemption issues in recent decisions is fully consistent with foundational and long-standing principles of constitutional law and statutory construction.

1. Notably, there is no basis in the text of the Constitution for a presumption against preemption in any circumstance. When Congress legislates within the scope of its enumerated powers, the Supremacy Clause renders these federal enactments "the supreme Law of the Land," U.S. CONST. art. VI, cl. 2, and "invalidates" "'interfer[ing]'" or "'contrary'" state law. *Hillsborough County*, 471 U.S. at 712 (quoting *Gibbons*, 22 U.S. at 211) (Marshall, C.J.). "[S]ince [the Court's] decision in *McCulloch* v. *Maryland*, [17 U.S. (4 Wheat.) 316, 427 (1819)], it has

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[11] In fact, harkening back to *Geier*'s reliance on "ordinary * * * principles of conflict pre-emption," 529 U.S. at 874, the *Sprietsma* Court pointedly characterized preemption as the *automatic* outcome of a direct conflict between a federal regulation and a state common law claim. See *Sprietsma*, 537 U.S. at 65 ("Of course * * * pre-emption would occur.").

been settled that state law that conflicts with federal law is without effect." *Cipollone*, 505 U.S. at 516 (internal quotation marks omitted).

Against the backdrop of this well-established framework rooted in the text of the Constitution, the Court has characterized the presumption against preemption as justified by "federalism concerns." *Lohr*, 518 U.S. at 485. It provides "assurance that the federal-state balance will not be disturbed unintentionally by Congress or unnecessarily by the courts." *Jones*, 430 U.S. at 525 (internal quotation marks and citation omitted); see also *Geier*, 529 U.S. at 907 (Stevens, J., dissenting) (presumption is necessary to allow "the structural safeguards inherent in the normal operation of the legislative process [to] operate to defend state interests from undue infringement").

But this justification is not universally recognized even in the express preemption context. See, *e.g.*, *Cipollone*, 505 U.S. at 544 (Scalia, J.) ("Under the Supremacy Clause, [the Court's] job is to interpret Congress's decrees of pre-emption neither narrowly nor broadly, but in accordance with their apparent meaning.") (citation omitted). More generally, the Supremacy Clause would itself appear to have resolved the invoked "federalism concerns" by establishing an unambiguous and bright-line constitutional rule for how federal and state law are to relate. Indeed, the Court has reiterated that "[u]nder the Supremacy Clause * * * the relative importance to the State of its own law is not material when there is a conflict with a valid federal law, for any state law, however clearly within a State's acknowledged power, which interferes with or is contrary to federal law, must yield." *Felder* v. *Casey*, 487 U.S. 131, 138

(1988) (internal quotation marks omitted); see also *De Canas* v. *Bica*, 424 U.S. 351, 357 (1976) ("even state regulation designed to protect vital state interests must give way to paramount federal legislation").[12] Accordingly, as Professor Viet Dinh has argued, the Court's "systematic[] favor[ing]" of "one result over another" in analyzing preemption questions "risk[s] an illegitimate expansion of the judicial function" by "disrupt[ing] the constitutional division of power between federal and state governments, rewrit[ing] the laws enacted by Congress, or both." Viet D. Dinh, *Reassessing the Law of Preemption*, 88 GEO. L.J. 2085, 2092 (2000).

As a matter of constitutional history, moreover, there is "no significant support * * * for the conclusion that the [F]ramers intended any * * * presumption to be read into [the Supremacy Clause]." Marin R. Scordato, *Federal Preemption of State Tort Claims*, 35 U.C. DAVIS L. REV. 1, 30 (2001). This is unsurprising given that the Framers' specific intention in designing the Supremacy Clause was "to remedy one of the chief defects in the Articles of Confederation by instructing courts to resolve state-federal conflicts in favor of federal law." David Sloss, *Constitutional Remedies for Statutory Violations*, 89 IOWA

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[12] Indeed, to the extent that the federalism justification for the presumption rests on emanations from the Tenth Amendment, it would appear to be at odds with the decision last Term in *Watters* v. *Wachovia Bank, N.A.*, 127 S. Ct. 1559 (2007), in which the Court squarely held that the Tenth Amendment "is not implicated" in the preemption analysis because "'if a power is delegated to Congress in the Constitution, the Tenth Amendment expressly disclaims any reservation of that power to the States.'" *Id.* at 1573 (quoting *New York* v. *United States*, 505 U.S. 144, 156 (1992)).

L. REV. 355, 402 (2004). Recent historical research suggests that this intention was built into the Supremacy Clause itself: the Framers would have understood the Supremacy Clause's *non obstante* clause—"any thing in the Constitution or Laws of any State to the contrary notwithstanding"—as *rejecting* "a general presumption that federal law does not contradict state law." Caleb Nelson, *Preemption*, 86 VA. L. REV. 225, 293 (2000); see *id.* at 238–244, 254–260.

2. Despite these unresolved challenges to the presumption's theoretical foundations, the Court's decisions indicate that its invocation may be justified when a court must *infer* Congress's preemptive intent or purpose. See *Smiley* v. *Citibank (S.D.), N.A.*, 517 U.S. 735, 744 (1996) (presumption applicable in determining "whether a statute is pre-emptive").

Both express and field preemption analyses may require such an inference in the first instance. Express preemption analysis generally involves judicial interpretation of "explicit statutory language," *English*, 496 U.S. at 79, to determine whether it supplies an "express statement of pre-emptive intent," *Geier*, 529 U.S. at 884, and to "identify the domain" that Congress "intended" to invalidate by that statement. *Lohr*, 518 U.S. at 484–485 (internal quotation marks omitted).[13] Likewise, courts in field preemption cases look for support in the "substantive provisions of the

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[13] In such cases, the presumption affords a rule for construing the express preemption provision. See, *e.g.*, *Cipollone*, 505 U.S. at 518 ("we must construe these provisions in light of the presumption against * * * pre-emption"); *Bates*, 544 U.S. at 449 (presumption against preemption imposes "duty" on court "to accept the reading" of statutory preemption provisions "that disfavors preemption").

legislation," *Cipollone*, 505 U.S. at 517 (internal quotation marks omitted), for the inference that "Congress intends that federal law occupy a given field." *ARC Am. Corp.*, 490 U.S. at 100.[14]

As the Court has explained, however, "conflict pre-emption is different." *Geier*, 529 U.S. at 884. Conflict preemption does not turn on a judicial inference of Congress's preemptive intent; indeed, an actual conflict resulting in preemption may be found "[w]here Congress likely did not focus specifically on the matter." *Lohr*, 518 U.S. at 504 (Breyer, J.). Rather, conflict preemption turns "on the identification," based on "clear evidence," "of 'actual conflict'" between federal and state law. *Geier*, 529 U.S. at 884–885 (quoting *English*, 496 U.S. at 78–79).[15]

The existence of an "actual conflict" is a "question of the substantive (as opposed to preemptive) *meaning* of a statute"—an inquiry that, as the Court has explained, "does not bring into play" the presumption against preemption. *Smiley*, 517 U.S. at 744.[16] Application of a presumption against preemp-

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[14] See also *Hillsborough County*, 471 U.S. at 714 ("The question whether the regulation of an entire field has been reserved by the Federal Government is, essentially, a question of ascertaining the intent underlying the federal scheme.").

[15] See also *Ouellette*, 479 U.S. at 491 (distinguishing judicial "inference" of preemption, which courts should not undertake "lightly," from situation presenting "actual[] conflict[]") (internal quotation marks omitted).

[16] See also *Brown*, 468 U.S. at 503 ("[w]here, as here, the issue is one of an *asserted substantive conflict* with a federal enactment, then the relative importance to the State of its own law is not material") (emphasis added; internal quotation marks and alterations omitted); *Fid. Fed. Sav. & Loan Ass'n* v. *de la Cuesta*, 458 U.S. 141, 153 (1982) (holding that principles of con-

tion rooted in "structural safeguards" of federalism, *Geier*, 529 U.S. at 907 (Stevens, J., dissenting), would be particularly inappropriate when courts interpret Congress's substantive enactments because "Congress's chosen level of deference to state interests will be reflected in the language that Congress enacts." Nelson, 86 VA. L. REV. at 302. Applying the presumption would be "to give the * * * safeguards * * * a kind of double weight." *Id.* at 300. Accordingly, in a number of cases presenting issues of conflict preemption, this Court instead has applied its standard interpretive methods to arrive at broad constructions of substantive statutory meaning.[17]

Thus, a court's interpretation of the substantive meaning of statutory language must not be "confuse[d]" with a court's distinct inference as to whether, and to what extent, Congress intended to legislate preemptively. *Smiley*, 517 U.S. at 744. Since it is only with respect to the latter that the presumption against preemption can mandate congressional clarity—and because the latter may only be at issue in the express- and field- preemption contexts—there is no warrant for invoking the presumption to analyze whether state and federal law are in actual conflict.

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flict preemption are "not inapplicable * * * simply because [state law at issue] is a matter of special concern to the States").

[17] See, *e.g.*, *Watters*, 127 S. Ct. at 1567 ("We have 'interpreted grants of both enumerated and incidental 'powers' to national banks as grants of authority not normally limited by, but rather ordinarily pre-empting, contrary state law.'") (quoting *Barnett Bank of Marion Cty., N. A.* v. *Nelson*, 517 U.S. 25, 32 (1996)); *Allied-Bruce Terminix Cos.* v. *Dobson*, 513 U.S. 265, 275 (1995) (adopting "broad interpretation" of substantive language determining coverage of Section 2 of the Arbitration Act despite preemptive effect on conflicting state law).

3. Of course, once an actual conflict has been identified as a matter of substantive law, the Supremacy Clause requires the "nullifi[cation]" of the contrary state law, *Hillsborough County*, 471 U.S. at 713, no matter how "clearly within [the] State's acknowledged power" the law is, *Felder*, 487 U.S. at 138 (internal quotation marks omitted). See *Geier*, 529 U.S. at 873; *Irving*, 136 F.3d at 769; *Perry*, 957 F.2d at 1261-1262. Indeed, "[a] holding of federal exclusion of state law [at that point] is inescapable and requires no inquiry into congressional design." *Fla. Lime & Avocado Growers, Inc.* v. *Paul*, 373 U.S. 132, 142–143 (1963).

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There is no basis in this Court's precedents, foundational principles of constitutional law, or the structure of our federal system for a court to invoke a presumption against preemption when analyzing a claim of conflict preemption. Straightforward application of the Supremacy Clause, by contrast, facilitates the realization of Congress's objectives and affords private actors—particularly in regulated fields—an important measure of legal certainty and predictability.[18] The "day" has come for the Court to "consider[]" the presumption in the conflict preemption context, *Crosby*, 530 U.S. at 374 n.8, and to hold that the presumption has no applicability there.

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[18] *See Geier*, 529 U.S. at 874 (noting the "legal uncertainty," and consequent "inevitable systemwide costs," imposed by an unnecessarily "complicated" preemption analysis); cf. *Cent. Bank* v. *First Interstate Bank*, 511 U.S. 164, 188 (1994) (noting "undesirab[ility]" of judicial "decisions made on an ad hoc basis, offering little predictive value") (internal quotation marks omitted).

II. The Presumption Against Preemption Would Not Apply In This Case Even Were It Ever To Apply To A Conflict Preemption Analysis.

Even were the presumption against preemption ever to apply in analyzing the question whether state and federal law are in actual conflict, but see Part I, *supra*, that presumption would nonetheless be inapplicable in this case. Rather than involving an area in which the States have long regulated, the state law at issue in this case is of recent vintage and plainly intrudes upon the inherently federal regulation of pharmaceutical companies by the FDA. Thus, the application of the presumption against preemption here would be unwarranted and could have undesirable consequences in a wide variety of situations.

A. The Michigan immunity exception trenches on an inherently federal relationship.

Because the state law at issue here necessarily intrudes on the inherently federal regulation of pharmaceuticals, under this Court's precedents the presumption against preemption should not apply.

1. Although this Court has not clearly delineated the circumstances in which the presumption against preemption may be invoked in a preemption analysis, the guidance that the Court has provided demonstrates that no such presumption is warranted here.

First, it is clear under this Court's precedents that the presumption is concerned primarily with "state police power regulations," *Cipollone*, 505 U.S. at 518, a category that in certain circumstances may

include "state-law causes of action." *Lohr*, 518 U.S. at 485; see also *Cipollone*, 505 U.S. at 523 (invoking presumption in determining whether "common-law claims" are preempted).

Second, even where there is such a regulatory state law at issue, the presumption applies only if the "area" in which the state law "regulates," *Locke*, 529 U.S. at 108, is one that "'the States have traditionally occupied.'" *Buckman*, 531 U.S. at 347 (quoting *Rice*, 331 U.S. at 230); see also *ARC Am. Corp.*, 490 U.S. at 101 (describing "presumption against finding pre-emption of state law in areas traditionally regulated by the States"). In particular, the presumption against preemption does not apply "when the State regulates in an area where there has been a history of significant federal presence." *Locke*, 529 U.S. at 108.

As the Court emphasized in *Buckman*, there is no presumption against preemption—and state law cannot be characterized as regulating in "a field which the States have traditionally occupied"—when a state law also can be characterized as "[p]olicing fraud against federal agencies." 531 U.S. at 347 (internal quotation marks omitted). This is so because "the relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law." *Ibid.* (citing *Boyle* v. *United Techs. Corp.*, 487 U.S. 500, 504–505 (1988)); see also *id.* at 347–348 ("petitioner's dealings with the FDA were prompted by [federal law], and the very subject matter of petitioner's

statements were dictated by that [federal law's] provisions").[19]

The Court in *Buckman* thus focused on the *nature* of the relationship between a federal agency and a regulated entity—a relationship completely defined by "federal enactments" that constituted "a critical element in [plaintiffs'] case." 531 U.S. at 353.[20] Preemption of state law that "bear[s] upon" a relationship of such a federal nature, *Locke*, 529 U.S. at 108, poses no threat to "the historic primacy of state regulation of matters of health and safety" and, accordingly, does not warrant the presumption. *Buckman*, 531 U.S. at 348 (internal quotation marks omitted).

2. This case is not materially distinguishable from *Buckman* for purposes of determining whether a presumption against preemption should apply. The Michigan immunity exception relies on a showing that, like the cause of action at issue in *Buckman*, facially implicates the substance and propriety of the manufacturer's relationship with the FDA. See MICH. COMP. LAWS § 600.2946(5). There is no basis

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[19] Applying principles of conflict preemption, the Court determined in *Buckman* that federal law preempted state law tort claims alleging (i) that a defendant consulting company had "made fraudulent representations to the [FDA] in the course of obtaining approval" to market a medical device and (ii) that "such representations were at least a but for cause" of the plaintiffs' injuries. 531 U.S. at 343 (internal quotation marks omitted).

[20] Cf. *Chicago & Nw. Transp. Co.* v. *Kalo Brick & Tile Co.*, 450 U.S. 311, 317–318 (1981) ("in deciding whether any conflict is present, a court's concern is necessarily with the *nature of the activities which the States have sought to regulate*, rather than on the method of regulation adopted") (emphasis added; internal quotation marks omitted).

for arguing that the nature of the relationship between the manufacturer of a new drug and the FDA is any less "inherently federal in character" than the relationship between a medical device manufacturer (or its consultant) and the FDA in *Buckman*. 531 U.S. at 347. Rather, as petitioner has amply demonstrated, see Pet. Br. 3–11, federal law (i) "sets forth a comprehensive scheme" for determining if an applicant's new drug is entitled to FDA approval and specifying what the terms of that approval will be, *Buckman*, 531 U.S. at 348, and (ii) accords the FDA the same authorities to "detect[], deter[], and punish[] false statements made during" the approval process that this Court recognized in *Buckman*. *Id.* at 349. Accordingly, as in *Buckman*, there can be no question that federal law "prompted" "petitioner[s'] dealings with the FDA," and that "the very subject matter of petitioner[s'] statements [to the agency] were dictated by" the "provisions" of federal law. *Id.* at 347–348.

Nor is there any relevant basis for distinguishing a cause of action predicated on a finding of fraud on the FDA, as in *Buckman*, from the fraud-on-the-FDA exception to a generalized grant of statutory immunity from common law liability that is at issue here. As the Sixth Circuit has noted, the difference between the two forms of state regulation is "immaterial." *Garcia* v. *Wyeth-Ayerst Labs.*, 385 F.3d 961, 965–966 (6th Cir. 2004). Both create a predicate requirement to establishing liability under state tort law that directly and manifestly turns on a state court's independent inquiry into the adequacy and veracity of submissions to the FDA.

There can be no doubt that such a requirement "bear[s] upon," *Locke*, 529 U.S. at 108, a relationship

that is "inherently federal in character." *Buckman*, 531 U.S. at 347. To "bear" means, *inter alia*, "to relate or have relevance" or "to exert influence or force." MERRIAM-WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY 191 (1986); see also, *e.g.*, *Allen-Bradley Local No. 1111* v. *Wis. Employment Relations Bd.*, 315 U.S. 740, 749 (1942) ("ha[s] an impact on"); *Boyle*, 487 U.S. at 506 ("implicate[s]"). That the relationship between the manufacturer and the FDA is mentioned on the very face of the statutory provision demonstrates conclusively that this standard is satisfied here.

Moreover, if, as here, the FDA has approved an allegedly defective drug and the drug and its labeling complied with that approval at the time of distribution, plaintiffs asserting product liability claims under Michigan law *must* allege fraud on the FDA for their cases to go forward; otherwise, their claims cannot survive under the statutory immunity provision. See MICH. COMP. LAWS § 600.2946(5). For such plaintiffs, the immunity exception renders "the existence of the[] federal enactments * * * a critical element in their case," which was the defining characteristic of the claims asserted in *Buckman* for purposes of the overall preemption analysis. 531 U.S. at 353; cf. *Grable & Sons Metal Prods., Inc.* v. *Darue Eng'g & Mfg.*, 545 U.S. 308, 312 (2005) (noting federal interest in "claims recognized under state law that nonetheless turn on substantial questions of federal law").

Indeed, by hinging liability on Michigan's independent evaluation of the relationship between the FDA and the defendant pharmaceutical manufacturer, the immunity exception actually transforms the duty of such manufacturers to comply with FDA

new drug approval requirements—a duty that is entirely the creation of federal law—into a matter directly subject to concurrent regulation under state tort law. But as the *Buckman* Court recognized, such regulation necessarily presents the possibility that a state judge or jury will conclude that FDA approval of a drug was fraudulently induced, even where the FDA has drawn no such conclusion, or, indeed, has arrived at a contrary conclusion. 531 U.S. at 350. There can be no presumption against preemption when the state casts the "shadow of [its] tort regime[]" over a federal regulatory scheme. *Ibid.*

Thus, a state cannot conduct such a direct intrusion into the federal realm without losing any entitlement to the presumption against preemption that it might enjoy when it regulates solely in those fields that it has "traditionally occupied." *Buckman*, 531 U.S. at 347.

B. The court of appeals mischaracterized the nature of the preemption at issue in this case and did not apply the analysis mandated by this Court's precedents.

In determining that the issue presented by this case warranted invocation of a presumption against preemption, the Second Circuit purported simply to be following the precedents of this Court. See Pet. App. 18a–19a (citing to *Buckman* and *Lohr*). The rationale underlying the court of appeals' approach, however, misinterprets and directly contradicts a number of this Court's precedents, and the approach—if allowed to stand—would work a dramatic and improper expansion of the circumstances triggering the presumption.

1. As a preliminary matter, the court of appeals inaccurately characterized the preemption issue, citing the proposition that "'Congress does not cavalierly pre-empt state-law *causes of action*.'" Pet. App. 18a (quoting *Lohr*, 518 U.S. at 485) (emphasis added).[21] But this case does not involve the preemption by federal law of any state-law cause of action; rather, as the court of appeals seemed at one point to recognize, at issue is whether federal law impliedly preempts a statutory exception to *immunity* from liability. See Pet. App. 27a ("we conclude that the Michigan immunity exception is not prohibited through preemption"); see also *Garcia*, 385 F.3d at 966 ("*Buckman* prohibits a plaintiff from invoking the *exceptions* on the basis of state court findings of fraud on the FDA.") (emphasis added and removed).

Plaintiffs' product liability claims sound in Michigan's traditional common law of tort, not in any cause of action created by the immunity exception itself. See Pet. App. 18a ("[MICH. COMP. LAWS

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[21] See also Pet. App. 20a & n.7 ("were we to conclude that Appellants' claims were preempted, we would be holding that Congress, without any explicit expression of intent, should nonetheless be taken to have modified (and, in effect, gutted) traditional state law duties between pharmaceutical companies and their consumers"); *id.* at 3a ("Historically, common law liability has formed the bedrock of state regulation, and common law tort claims have been described as 'a critical component of the States' traditional ability to protect the health and safety of their citizens.'") (quoting *Cipollone*, 505 U.S. at 544) (Blackmun, J.); *id.* at 27a ("Because of its important role in state regulation of matters of health and safety, common law liability cannot be easily displaced in our federal system."); *ibid.* ("The appeal before us presents a very different set of circumstances, one in which there is a clear presumption against preemption of long-standing common law claims.").

§ 600.2946(5)] did not invent new causes of action premised on fraud against the FDA."). A finding that federal law preempts the immunity exception would result in plaintiffs' claims being extinguished (assuming severability, see *Garcia*, 385 F.3d at 967); but it would be *state law*—the statutory immunity shorn of the exception—that would be responsible, not federal law. Accordingly, federal preemption in the case at bar would itself preclude no plaintiff from asserting a state law cause of action. Indeed, a finding of preemption would impose no restrictions on the power of the Michigan legislature to repeal the statutory immunity to product liability suits that it has granted drug manufacturers, thereby potentially allowing such suits to go forward under traditional state law causes of action.[22] That in and of itself precludes the conclusion of the court of appeals that the presumption "stands at its strongest" here, Pet. App. 19a. See *Merrill Lynch, Pierce, Fenner & Smith, Inc.* v. *Dabit*, 547 U.S. 71, 87 (2006) (holding "that presumption carries less force" where federal law "does not actually pre-empt any state cause of action").

The Second Circuit's confusion as to the nature of the preemption at issue in this case also explains its misguided reliance on the observation that "the cause of action (which survives the changes made by [MICH. COMP. LAWS] § 2946(5)) cannot reasonably be characterized as a state's attempt to police fraud against the FDA." Pet. App. 18a. Nothing in *Buckman* suggests that the presumption-against-preemption inquiry turns on the characterization of the underlying state law cause of action, as opposed

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[22] Other forms of preemption might still be applicable in that instance, however.

to the characterization of the state law that actually is subject to preemption. In *Buckman*, because the state law at issue happened to be a cause of action, the characterization of that cause of action was relevant. In this case, however, the state law subject to preemption is the exception to statutory immunity, so the characterization of that immunity exception is what matters. As we demonstrated above (at 26-27), since the immunity exception clearly bears upon an inherently federal relationship, there should be no presumption against preemption here.

2. The court of appeals ultimately concluded that the presumption against preemption "stands at its strongest" in this case because "[t]he Michigan legislature's desire to rein in state-based tort liability falls squarely within its prerogative to regulate matters of health and safety." Pet. App. 19a (internal quotation marks and alterations omitted). That reasoning, too, is flawed for at least two reasons.

First, the court of appeals sought to discern the Michigan legislature's motivation in enacting the immunity exception. See Pet. App. 19a (evaluating legislature's "desire"); see also *id.* at 19a n.5 (finding "no evidence that the goal of preventing or punishing fraud against the FDA in any way motivated Michigan legislators to enact the statutory framework in question"). This Court, however, has squarely rejected reliance on this sort of review of a legislature's motivations in analyzing preemption issues. As the Court recognized over 35 years ago, it would be "aberrational" to allow "state law [to] frustrate the operation of federal law as long as the state legislature in passing its law had some purpose in mind other than one of frustration." *Perez* v. *Campbell*, 402 U.S. 637, 651-652 (1971); see also, *e.g.*, *Gade*, 505 U.S. at

105 (plurality) ("[i]n assessing the impact of a state law on the federal scheme, we have refused to rely solely on the legislature's professed purpose").

As the Court's precedents recognize, the Second Circuit's motive-based approach is unwise because, among other reasons, it would make the applicability of the presumption against preemption hinge on the state legislature's unilateral characterization of state law—a characterization that state lawmakers could manipulate easily. See *Perez*, 402 U.S. at 652 (rejecting "doctrine" that "would enable state legislatures to nullify nearly all unwanted federal legislation by simply publishing a legislative committee report articulating some state interest or policy"). Nor is there any support in *Locke* or *Buckman* for the proposition that whether state law bears upon an inherently federal relationship turns on the motivation of state lawmakers.

Second, the court of appeals ignored *Buckman*'s primary lesson in applying the presumption against preemption: state law that bears upon an inherently federal relationship cannot threaten "the historic primacy of state regulation of matters of health and safety." *Buckman*, 531 U.S. at 348 (internal quotation marks omitted).

Both the fraud-on-the-FDA cause of action at issue in *Buckman* and the fraud-on-the-FDA immunity exception at issue here establish the terms of liability under state tort law, and thus both can be characterized as implicating "matters of health and safety." *Lohr*, 518 U.S. at 485; see also *Geier*, 529 U.S. at 894 (Stevens, J., dissenting) (describing "provision of tort remedies to compensate for personal injuries" as type of state law that is "within the scope of the States' historic police powers").

But state regulation implicating matters of health and safety is entitled to the presumption against preemption *only* when it also can be characterized as falling within a "field" that "the States have traditionally occupied." *Buckman*, 531 U.S. at 347 (internal quotation marks omitted); see also *Locke*, 529 U.S. at 107; *Geier*, 529 U.S. at 907 (Stevens, J., dissenting).[23] Such a characterization is impossible here given the direct intrusion on an inherently federal relationship. See Part II.A.2, *supra*. Indeed, as with the fraud-on-the-FDA cause of action at issue in *Buckman*, the immunity exception, which turns on a demonstration of fraud on a federal agency, necessarily cannot have predated the creation of that federal agency by federal law. See *Buckman*, 531 U.S. at 353 ("the fraud claims exist solely by virtue of the FDCA disclosure requirements").

As a practical matter, the court of appeals' approach, if allowed to stand, would permit States to circumvent *Buckman*'s limits on statutory causes of action that implicate inherently federal relationships by establishing, and then fine-tuning through myriad exceptions, statutory immunities to traditional state common law causes of action. Perversely, by encouraging accretion of immunities and exceptions to those immunities, such an approach in practice would inevitably result in complex state regulatory schemes that sweep broadly and disrupt a wide swath of traditional common law claims in order to

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[23] Cf. *Felder*, 487 U.S. at 138 (no mention of presumption against preemption in finding preemption of state rule of judicial procedure that conflicted with objectives of federal law, despite Court's acknowledgment of "the general and unassailable proposition * * * that States may establish the rules of procedure governing litigation in their own courts").

achieve limited regulatory goals. A simple rule that precludes invocation of the presumption against preemption whenever state law directly and manifestly bears upon an inherently federal relationship is both more consistent with this Court's precedents and far more rational. Such a rule will leave the States ample leeway to pursue their regulatory objectives.

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted.

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